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May 31, 2005

Dockets Management Branch  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20857

### CITIZEN PETITION

The Allentown Health Bureau submits this petition pursuant to §4(d) of the Administrative Procedures Act, 5 U.S.C. §553(e), and §§401, 403(a)(1) and (g), and 701(a) of the Federal Food Drug and Cosmetic Act, 21 U.S.C. §§341, 343(a)(1) and (g) and 371(a), and 21 C.F.R. §§10.30, to request the Commissioner of the Food and Drug Administration (FDA) to amend the regulations governing the labeling of milk products that are set out in Part 131 of Title 21 of the Code of Federal Regulations.

#### A. *Action requested*

The Allentown Health Bureau requests the Commissioner to revise its regulations as follows:

1. In 21 C.F.R. §131.110(e) (1), substitute the phrase "accompany the name of the food" with "shall follow the name of the food on a separate line," and the phrase "not less than" with the phrase "not more than," and delete the phrases "vitamin A" and "vitamin D" as follows:

"(1)The following terms shall follow the name of the food on a separate line wherever it appears on the principal display panel or panels of the label in letters not more than one-half of the height of the letters used in such name:

(i) If vitamins are added, the phrase "vitamin A added" or "vitamin D added," or "vitamins A and D added," as is appropriate."

2. Make similar revisions, where appropriate, in Part 131.<sup>1</sup>

<sup>1</sup> Our main concern in this petition is with the milk products that are most widely consumed, which is why we have focused on the standard of identity for milk. However, in order to make its regulations and nomenclature consistent, FDA should make the revision that is requested in this petition in all appropriate standards (e.g., the standard of identity for acidified milk (21 C.F.R. §131.111) and for cultured milk (21 C.F.R. §131.112)).



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3. In 21 C.F.R. § 1.24(a)(7)(i)) and any other FDA regulations where the term “vitamin D milk” currently appears, substitute the phrase “vitamin D milk” with “whole milk.”

## *B. Statement of grounds*

### **1. Factual Grounds**

In the first three decades of the 20<sup>th</sup> century, food production and packaging in America were undergoing dramatic technological advancement. Among the marvels of technology perfected at that time was the bottling and distribution of milk. Not only was the bottled milk tremendously convenient, it also was homogenized and fortified with Vitamin D. There was only one variety being sold (whole milk), and it was named “Vitamin D Milk.” America was thriving, and it was a very rare American child who was considered overweight. The major cause of death was infectious disease.

Now, in 2005, obesity in American children is epidemic, type 2 diabetes in children is increasing in incidence, and heart disease is the number one killer of American men and women. An important goal of public health programs to combat these chronic diseases – along with efforts to prevent osteoporosis -- is to encourage adequate calcium intake in the diet along with decreased consumption of fat, especially saturated fat.

Today, milk is sold in various sizes of plastic and paper containers, and there are four main varieties on the market : whole, 2%, 1% and fat free. As a healthful part of a balanced diet, nutritionists and public health advocates recommend the daily intake of milk, but because of the impact of saturated fat consumption on chronic disease, all people over the age of two are advised to consume “fat free” (“skim”) or low fat (1%) milk. Yet, 67% of all milk sales remain whole and 2% milk (International Dairy Foods Association, “Dairy Facts” p.83).

Professional observation, anecdotal evidence and consumer surveys point to the influence of the original nomenclature “Vitamin D Milk” on the continued popularity of whole milk. In hindsight, this nomenclature was a marketing miracle of its time. Consistent through the years, “Vitamin D Milk” remains the preeminent “right” choice in the minds of many. Perhaps protected in its niche as number one in sales by the industry-wide practice of using that bold and simple name: “Vitamin D Milk,” it is what consumers reach for in the milk aisle despite the other options. It is therefore not surprising that, nationally, 65% of dairies use the name “Vitamin D Milk” on their whole milk labels. (Allentown Health Bureau surveys– see Appendix A).

What many consumers do not realize is that lower- fat milks are nutritionally equivalent to full-fat milk except that they contain less calories and less fat. Somehow the belief persists that the original “Vitamin D Milk” is best and anything else is less (CDC’s

Chronic Disease Notes and Reports Volume 13 Number 1 Winter 2000). In fact, lower fat milks have the same amount of Vitamin D.

Surveys demonstrate that this misconception persists:

- In 2002, the Allentown Health Bureau conducted a consumer survey investigating how consumers understand the nutritional content of the milk varieties. Using a sample size (n=100) and demographic developed by a local university, the survey found that 75% of the consumers used whole milk and 71% of those either believed or were unsure whether whole milk is the only type of milk that contains vitamin D. (See Appendix A)
- Studies conducted by Roper Starch Worldwide reported that “less than half [of surveyed adults] realize that skim milk contains the same nutrients [as whole milk] and with just the fat removed” (Journal of the American Dietetic Association, November 2001 Volume 101 Number 11, p 1312).
- Sixty-six percent of registered dietitians responding to an e-mail listserv question agreed that the name “Vitamin D Milk” should be changed because in their experience, consumers follow the mistaken belief in the nutritional superiority of whole milk. (See Appendix A).

The changes requested in this petition will be particularly helpful to low income/non English-speaking consumers: Experts note that the belief that reduced-fat milk contains less calcium/vitamin D than whole milk is particularly prevalent among Spanish-speaking Hispanics (Journal of the American Dietetic Association, November 2001 Volume 101 Number 11, p 1312).

Public Health professionals throughout the state of Pennsylvania who implemented the “1% or Less” Milk Campaign also found that low income/non-English speaking consistently look for and choose “Vitamin D Milk” because they believe it to be better than/superior to the other varieties. These consumers would not switch to low-fat milks until they were repeatedly assured of their nutritional equality (see Appendix A). Those who have implemented the 1% or Less Campaign in different geographic and demographic areas perceive the practice of calling whole milk “Vitamin D milk” as a barrier to the success of the campaign.

In November 1996, FDA took an important step toward helping consumers choose lower fat milk products by making the definitions of “low fat” and “reduced fat” milk consistent with the new nutrition labeling regulations. (61 Fed. Reg. 58991 (1996)) That action cleared up the confusion created by inconsistent definitions of “low fat.” This petition seeks to eliminate the lingering confusion caused by use of the term “Vitamin D Milk” for whole milk. The revisions to FDA rules that we are requesting would improve the consistency and uniformity of labeling not just with other low fat products but between different milk varieties. Our goal is to facilitate, through clearer labeling, healthier choices by consumers when they are purchasing milk.

## **2. Legal Grounds**

FDA has ample authority to take the actions requested in this petition under various provisions of the Federal Food Drug and Cosmetic Act ("the Act").

Section 401 of the Act provides FDA with the authority to establish standards of identity which, among other things, specify nomenclature to be used on product labels. Section 403(g) provides that a food subject to a standard of identity will be misbranded unless its label bears the name of the food specified in the definition and standard.

Section 403 also contains a general provision that prohibits labeling that is "false or misleading in any particular." 21 U.S.C. §343(a) (1). In determining whether labeling is misleading, section 201(n) of the Act, 21 U.S.C. §321(n), states that "representation made or suggested by statement, word, design, device, or any combination thereof" shall be taken into account. The survey data discussed above clearly demonstrates that allowing whole milk to be labeled "Vitamin D Milk" continues to mislead consumers that this product is the only milk product that contains this key nutrient. As a result, consumers are failing to switch to lower-fat milk products that have the same vitamin fortification but far less saturated fat. According to the Dietary Guidelines for Americans 2005, whole and 2% milk are among the top three contributors of saturated fat in Americans' diets (JADA, June 2004 Volume 104 Number 6, p.926). By granting the action requested in this petition, FDA would be taking one small but important step toward reducing saturated fat consumption and thereby lowering the risk of heart disease and other chronic, diet-related diseases.

Finally, Section 701(a) of the Act authorizes the agency to adopt (and revise) regulations for the "efficient enforcement of this Act."

### **C. *Environmental impact***

The action requested in this petition is categorically excluded from the requirement for the preparation of an environmental impact statement under 21 C.F.R. §25.32(a).

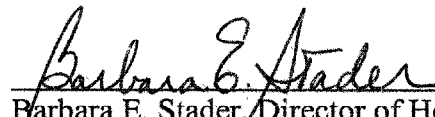
D. *Certification*

The undersigned certify, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioners which are unfavorable to the petition.

Respectfully Submitted,



Tina Amato, Registered Dietitian  
Chronic Disease Manager



Barbara E. Stader, Director of Health

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## Appendix A

### Survey Results to Support a Petition to the FDA Conducted by the Allentown Health Bureau

<p><b>Consumer Survey</b> November 2002 Allentown, PA (100 Consumers)</p> <p>75% use whole milk:</p> <ul style="list-style-type: none"> <li>• 22% of those refer to it as "Vitamin D" milk</li> <li>• 71% of whole users either believed or were not sure whether whole milk is the only type of milk that contains vitamin D</li> </ul>	<p><b>Pennsylvania County &amp; Municipal Health Agencies Conducting 1% or Less Campaign</b> June 2003 (9 Agencies)</p> <p>Scale of 1 (seldom) to 5 (frequent):</p> <ul style="list-style-type: none"> <li>• Mean score measuring frequency of people calling whole milk "Vitamin D" – 3.8</li> <li>• Frequency of people calling it "red cap" – 3.4</li> <li>• Mean score measuring how often the respondents felt that they needed to clarify that all milk contains vitamin D - 4.1</li> <li>• 100% would support a petition to the FDA</li> </ul>	<p><b>Dietitian Survey</b> <b>American Dietetic Association Listserv</b> March 2003 (15 respondents)</p> <ul style="list-style-type: none"> <li>• 11 agreed the name "Vitamin D milk" should be changed</li> <li>• 10 would support a petition to the FDA</li> </ul>	<p><b>National Dairy Survey</b> November 2003 – January 2004 (141 Dairies)</p> <ul style="list-style-type: none"> <li>• 65% of the dairies surveyed use the name "Vitamin D Milk" on their whole milk labels</li> </ul>
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